

REMARKS

This amendment is responsive to the Office Action of November 14, 2008. Reconsideration and allowance of **claims 2-9, 11-12, and 15-22** are requested.

The Office Action

Claims 15-18 were rejected under 35 U.S.C. §101 as directed to non-statutory subject matter.

Claims 1-18 were rejected under 35 U.S.C. §103 as being unpatentable over Kendrick et al. (U.S. Patent Application Publication No. 2003/0206614) in view of Blumhofer et al. (U.S. Patent No. 6,865,253).

Discussion

Kendrick et al. discloses a method and system for alignment of medical radiation beams using a body frame. Prior to undergoing radiation therapy, a patient is placed in the bodyframe and a set of three-dimensional pre-procedural images are produced using CT imaging, MRI scans, or some other scanning method. The fiducial markers are located on the bodyframe and appear as reference marks on the image set. Later, after the tumor has been identified and localized in the bodyframe coordinate space, the patient is transferred to the therapy machine for treatment. The markers are sensed by a detector and their positions are localized by a computer in the radiation treatment machine space. The position of the tumor, defined in bodyframe space, is derived from the pre-procedural image data and combined with the marker position data to localize the tumor in detector space. Once the location of the image of the tumor is located in radiation treatment space from the position of the fiducials, the technician appropriately positions the patient and commences treatment.

Blumhofer et al. is substantially the same as Kendrick et al., except that the markers are on the patient rather than in the frame. But, once the technician has placed the tumor in the appropriate treatment position, the technician verifies that the tumor is still where it was when the 3D image was generated. Remember analyzing the 3D image and creating a radiation therapy plan require some time. The 3D images may have been generated hours or even days before the patient is placed

on the radiation therapy device. Especially in soft tissue, the tumor may have shifted. So Blumhofer et al. verified that the tumor is still where the 3D image shows. Particularly, Blumhofer et al. takes two 2D projection images from two substantially orthogonal directions. Blumhofer et al. synthesizes two projection images along the orthogonal directions. Blumhofer et al. compares the newly taken projection images each with the corresponding synthesized projection image to be sure the projection images, particularly the tumor, are aligned and, if not make appropriate adjustments.

The Kendrick et al. and Blumhofer et al. systems are very good, but neither addresses the problem addressed by the present application, nor provides a solution. As pointed out in the present application (note for example the first half of page 2), MR images are much better than CT images at distinguishing soft tissue. But, MR images are inherently distorted due to non-linearities in the magnetic fields, applied gradients, and the like. When a large area is imaged with MR in order to get the tumor and the fiducial marks in the same image, the inherent MR distortions may be such that the relative locations of the tumor and the fiducial cannot be determined within acceptable tolerances.

By way of background, MR scanners are typically designed to have optimum linearity adjacent the isocenter. As one moves outward from the isocenter, the non-linearities increase and the image suffers more geometric distortion.

The present application suggests determining an imageable region, typically round the isocenter, which has an acceptably low level of geometric distortion, termed the optimal FOV. A first image is generated with the tumor in the optimal FOV but probably not one or more fiducial markers. The patient is shifted a known distance and a second image is generated with the fiducial marker, but probably not the tumor, in the optimal FOV. Using the known shift distance, the first and second images are overlaid to create a composite image depicting both the tumor and the fiducial marker(s) all within the acceptably low geometric distortion tolerances.

This composite image could be used as the 3D image of either Kendrick et al. or Blumhofer et al. Thus, the present application describes an improvement in which the radiation therapy planning (RTP) 3D image can be the composite MR image which has been carefully constructed to assure that the tumor

and the fiducial markers are all depicted with an acceptably low level of geometric distortion.

35 U.S.C. § 101

Claims 15-18 have been amended and are now directed to statutory subject matter.

**The Claims Distinguish Patentably
Over the References of Record**

Claims 1-9, 11-12, and 15-22 are patentable over Kendrick et al. in view of Blumhofer et al.

Claim 11 has been placed in independent form but has not been substantively amended.

More specifically, regarding **claim 11**, Kendrick et al. does not disclose wherein at least one fiducial marker is applied to the body of the patient, means for acquiring a second magnetic resonance image at a shifted position relative to the first magnetic resonance image, wherein the fiducial marker is imaged at its accurate geometrical position, and an image processing system for merging the accurate geometrical position of the target and the accurate geometrical position of the fiducial marker in a single image. Kendrick et al. discloses a 3D image which could be an MR image. But there is no recognition that this 3D image will likely have geometrical distortion problems much less that the geometric distortion problems could be overcome by using a composite image created as described in claim 11.

The Examiner refers Applicant to paragraphs [0003], [0005], [0037], and the Abstract of Kendrick et al. But these portions of Kendrick et al. discloses a patient being placed in a bodyframe, having markers located on the bodyframe, and producing a set of pre-procedural three-dimensional images containing the anatomical target of the patient, the bodyframe, and the markers on the bodyframe. The anatomical target is then localized in the detector or radiation treatment (RT) space by using the pre-procedural image and location of the markers in the detector or RT space. The tumor is then positioned at the RT isocenter of the RT device. Alignment of the radiation treatment (RT) radiation beams and the tumor is computed from the distance between the target in the RT space and the pre-calibrated position of the

RT isocenter. Kendrick et al. does not disclose placing fiducial markers on the patient at a distance away from the anatomical target. Additionally, Kendrick et al. does not disclose acquiring a MR image of the anatomical target where the anatomical target is imaged at its accurate geometrical position and then acquiring a MR image of the fiducial marker where the fiducial target is imaged at its accurate geometrical position, different from the position of the anatomical target. Kendrick et al. also fails to disclose that the images of the anatomical target and the fiducial marker are merged in order to display the accurate geometrical positions of both the anatomical target and the fiducial marker in the same image.

Kendrick et al. does not disclose a second image at a shifted position, and merging the accurate geometrical position of the target and fiducial marker into a single image. The Office Action asserts that Blumhofer et al. discloses the subject matter in Col 6. Lines 29-33, 37-45, and 53-54 which disclose that a patient is prepositioned with respect to a linear accelerator and 2D x-ray images of the patient are take from different angles. The 2D images are then compared with like 2D images synthesized from the pre-procedural 3D image to verify alignment or determine any positioning error. **Contrary to the Examiner's assertion, the 2D images generated in Figures 5 and 6 of Blumhofer et al. are not merged or otherwise combined with each other.** Rather, they are each compared with a corresponding 2D image synthesized from the 3D image.

It is respectfully submitted that Blumhofer et al. does not disclose acquiring an MR image of the anatomical target where the anatomical target is at its accurate geometrical position and then taking a second MR image of a fiducial marker at its accurate geometrical position. Additionally, Blumhofer et al. does not disclose merging the first image of the anatomical target and the second image of the fiducial marker in order to produce a single image able to display the accurate geometrical positions of both the anatomical target and the fiducial marker.

Neither Kendrick et al., nor, Blumhofer at al. nor the combination disclose or suggest either generating a first image of an anatomical target at its accurate geometrical position or generating a second image of a fiducial marker at its accurate geometrical position or merging the two images in order to produce a single

image able to display the accurate geometrical positions of both the anatomical target and the fiducial marker.

Accordingly it is submitted that independent **claim 11** and **claim 12** and **20** which depends therefrom distinguishes patentable over the references of record.

Claim 2 calls for obtaining a first magnetic resonance image with an anatomical target nearer a magnetic isocenter, obtaining a second magnetic resonance image within a fiducial marker located nearer the magnetic isocenter, and merging the first and second images into a composite image. It is respectfully submitted that neither Kendrick et al., nor Blumhofer et al., nor the combination teach thereof, create such first or second images nor such a composite image. Also, the 2D projection images of Blumhofer et al. are x-ray images, not MR images.

Accordingly it is submitted that independent **claim 2** and **claims 3-9** which depends therefrom distinguishes patentable over the references of record.

Claim 15 calls for acquiring first magnetic resonance image with an anatomical target in a lower geometric distortion region and acquiring a second magnetic resonance image with a fiducial marker located in the lower geometric distortion region. It is respectfully submitted that neither Kendrick et al., Blumhofer et al., nor the combination teach acquiring two magnetic resonance images, one with an anatomical target and the other with a fiducial marker in the lower geometric distortion region.

Accordingly it is submitted that independent **claim 15** and **claims 16-17** and **19** which depends therefrom distinguishes patentable over the references of record.

Claim 18 calls for obtaining additional magnetic resonance images within a FOV with additional fiducial markers in the FOV of the MR scanner and merging the images into a composite image. It is respectfully submitted that neither Kendrick et al. nor Blumhofer et al., nor the combination thereof teach producing a single composite image from a plurality of images.

Accordingly it is submitted that independent **claim 18** therefrom distinguishes patentable over the references of record.

Regarding **claim 21**, neither Kendrick et al., nor Blumhofer et al., nor the combination teach a method for planning radiotherapy treatment using magnetic resonance (MR) images in which a composite image is created by merging an optimal FOV image of the target and an optimal FOV image of the fiducial marker by overlapping corresponding parts in the images that displays the accurate geometric positions of the anatomical target and the fiducial target.

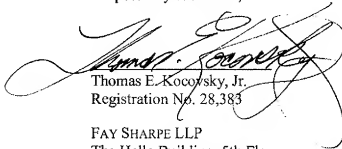
Regarding **claim 22**, neither Kendrick et al., nor Blumhofer et al., nor the combination teach a system including means for creating a composite image by overlapping a target image with an optimal FOV and a fiducial marker image with an optimal FOV by overlapping corresponding parts in the images, which composite image depicts the target and the fiducial marker with preselected geometrical accuracy.

CONCLUSION

For the reasons set forth above, it is submitted that **claims 2-9, 11-12, and 15-22** (all claims) distinguish patentably over the references of record and meet all statutory requirements. An early allowance of all claims is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, the Examiner is requested to telephone Thomas Kocovsky at 216.363.9000.

Respectfully submitted,



Thomas E. Kocovsky, Jr.
Registration No. 28,383

FAY SHARPE LLP
The Halle Building, 5th Floor
1228 Euclid Avenue
Cleveland, OH 44115-1843
Telephone: 216.363.9000 (main)
Telephone: 216.363.9122 (direct)
Facsimile: 216.363.9001
E-Mail: tkocovsky@faysharpe.com